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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/804,458	Applicant(s) MAHER ET AL.	
	Examiner Kaj K Olsen	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-8,10-16 and 19-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-8,10-16 and 19-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-19-2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

4. Claim 1 was amended to read on the embodiment of fig. 2A-2D and this claim no longer reads on the embodiment of fig. 8 and 9. It appears to the examiner that claims 14-16 (which depend from claim 1) were enabled only for the embodiment when the electrodes were perpendicular to the bottom surface of well. The examiner cannot find anything in the specification to suggest that the spacing of claims 14-16 were relevant to the embodiment of fig.

2. In fact, page 30, lines 2-6 appear to suggest that one would not want to space the electrodes too close together in order to accommodate the optical analysis. Clarification is requested.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 6-8, 10, 13-16 and 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Baer et al (USP 5,128,257). Baer is being utilized for the first time with this office action. Its use was necessitated by the amendment to the claims.

7. With respect to claim 1, Baer teaches an embodiment of an electrode assembly that has two electrodes (100, 102) that are parallel and non-overlapping and are disclosed as being placed into a well (i.e. a petri dish). See fig. 13 and col. 8, line 50 through col. 9, line 32. Although Baer does not explicitly state that the electrodes are adjacent to the bottom surface of the well, it is fairly clear that they are meant to be adjacent the bottom surface because the electrodes are mounted to a flat surface (col. 8, lines 58-60) and the only flat surface of a petri dish is the bottom surface of it (see fig. 2 as an example). Alternatively, in the event that Baer would not be construed as teaching the use of the bottom surface, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to place this electrode configuration adjacent to the bottom surface because the bottom surface would allow the flat electrode assembly to come in best contact with the sample within the petri dish. With respect to the limitation concerning the mean field intensity over the specified area, that is only the intended use of the apparatus and the intended use need not be given further due consideration in

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determining patentability. In addition, placing this electrode assembly adjacent the bottom of the well would clearly be capable of meeting the specified mean field intensity.

8. With respect to the claimed "assay plate", it doesn't appear that the applicant ever explicitly claims an assay plate and this plate thereby constitutes the intended use of the device (see alternative rejection with King below).

9. With respect to the use of high optically transparent materials, see col. 4, lines 24-26.

10. With respect to "up to 96 wells", this would appear to read on anything from 1 to 96 wells and Baer teaches at least one well.

11. With respect to the electrode material, see col. 8, lines 64-66.

12. With respect to the electrode spacing, see col. 9, lines 18-32.

13. With respect to claims 19-22, Baer also discloses embodiments where at least three substantially planar electrodes are all placed substantially parallel to each other perpendicular to the bottom surface of the well. See fig. 4, 6, 7, and 9 and col. 7, lines 4-25.

14. With respect to the charging of one of the electrodes, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

15. With respect to second and third pairs of electrodes, Baer only appears to explicitly disclose five total electrodes. However, Baer teaches that additional electrodes are anticipated (col. 6, lines 56-60). The use of additional electrodes would mean that there would be at least 6 electrodes and that would read on the claimed second and third pairs.

16. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnold et al (USP 4,801,543).

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17. These claims were previously rejected over Arnold (see details in the previous office action). These claims remain rejected over Arnold because the electrodes of Arnold are substantially planar. With respect to the additional electrode being substantially parallel to the pair of electrodes, applicant urges that Arnold does not teach this because the additional electrodes of Arnold are perpendicular to the pair of electrodes. In one dimension, this is correct. However, all the electrodes of Arnold still point towards the bottom surface of the well (i.e. they all point into the paper in fig. 1) and this still reads on the claimed parallel relationship.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 23-31, 24-39 and 41 are rejected over the teaching of Baer.

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21. Claims 23-31, 24-39 and 41 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Baer in view of Matschke (USP 4,699,881) or Hilliard et al (USP 4,695,547).

Both Matschke and Hilliard are being cited and relied on for the first time with this office action.

22. With respect to the new claims (those limitations not discussed above), Baer discloses all the limitations of the claim, but does not appear to disclose an assay plate having a well.

However, King already set forth that an electroporation can be performed on an assay plate having a series of wells (see rejection above). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of King for the well of the Baer because the use of a plate having a plurality of wells allows for simultaneous treatment of a number of samples.

23. With respect to the spacing of new claim 23, Baer does not explicitly recite a spacing from the bottom surface of the well to the bottom of the electrode. However, Baer does disclose appear to show that the electrodes lengths approximate the depth of the wells (see fig. 3 and 7 as an example), which would indicate the presence of a very small gap. Furthermore, Baer discloses that the cells in the petri dish are grown at the bottom of the well (col. 6, lines 7-9), which would indicate that if one is desiring to treat bottom grown cells with an electric field, one would want to extend the electrodes as close as possible to the bottom of the well. Based on these two suggestions of Baer, one possessing ordinary skill in the art would have been motivated to utilize a very small spacing, including a spacing between 0.1 to 0.5 mm, in order to ensure that the cells at the bottom of the well are suitably in the field lines for the electrodes.

24. Alternatively, Matschke discloses that a clearance 0.20 mm between an electrode and the bottom of the well was found to be a workable clearance in the art. See col. 5, lines 63-66.

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Hilliard discloses a clearance between the electrode and the walls of the well of 0.5 mm (col. 3, lines 13-17). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teachings of either Matschke or Hilliard for the electrode assembly of Baer and King in order to ensure the cells at the bottom of the well are within the electric field lines and these secondary teachings demonstrate that a 0.1 to 0.5 mm spacing was both known in the art and was mechanically feasible.

25. With respect to the electrode spacing for this embodiment of Baer, see col. 6, line 56 through col. 7, line 3.

26. With respect to the presence of an insulator, see fig. 7 and col. 5, lines 39-41.

27. Claims 11, 12, 32 and 33 (and claims 1, 3, 6-8, 10, 13-16, 23-31, 34-39, and 41 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Baer (with or without Matschke and Hilliard) in view of King et al (USP 6,352,853). King is being cited and relied on for the first time with this office action.

28. With respect to claims 11, 12, 32 and 33, Baer (with or without Matschke or Hilliard) disclosed all the limitations of the claims, but did not explicitly recite the use of greater than 96 or 384 wells. King discloses that an electroporation can be performed on a large scale by providing the samples to be electroporated in a plurality of wells, which allows simultaneous analysis of a number of samples while reducing the amount of materials needed for each analysis (col. 2, lines 50-65). The number of wells are typically multiples of 96, including 384 (col. 2, line 56). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of King for the electrode assembly of Baer (with or

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without Matschke or Hilliard) in order to reduce material waste and provide for simultaneous analysis of a plurality of samples.

29. With respect to the claims in the alternative, if the “assay plate” of these claims is construed as being part of the claimed invention and the petri dish of Baer is not construed as reading on an assay plate, then the sample well configuration of King would read on the assay plate. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of King for the electrode assembly of Baer because an plate having at least one well was known in the electroporation art as a means for holding sample and its use for the device of Baer would have required only routine skill in the art.

30. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baer (with or without the teachings of Matschke, Hilliard or King) in view of Papp et al (USP 5,422,272).

31. Baer and King (with or without the teachings of Matschke, Hilliard or King) set forth all the limitations of the claim, but did not explicitly recite the presence of two insulators substantially perpendicular to the bottom surface of the well. Papp teaches the presence of two insulators (7, 8) that are parallel to two electrodes in order to provide the desired spacing between the electrodes and to make the electrode more mechanically stable. See fig. 2A and col. 3, lines 45-50. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Papp for the electrode assembly of Baer (with or without the teachings of Matschke, Hilliard or King) in order to make the electrodes more mechanically stable.

Response to Arguments

32. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

33. With respect to the teaching of Arnold and claims 19-22, the examiner addressed that argument above in the actual rejection.

Conclusion

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 6:30 A.M. to 4:00 P.M. and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a stylized flourish extending from the end.

Kaj Olsen Ph.D.
Primary Examiner
AU 1753
July 1, 2004